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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

HELSINN HEALTHCARE S.A,

Plaintiff,

v.

SAGENT PHARMACEUTICALS, INC.,

Defendant.

CA. No. 2-16-cv-00173 SRC-CLW
CA. No. 3-16-cv-00681 MLC-DEA

Filed Under Seal
Oral Argument Requested

BRIEF IN SUPPORT OF SAGENT'S MOTION FOR AN ORDER TO SHOW CAUSE TO REOPEN THE CASES TO ENFORCE THE SETTLEMENT AGREEMENT

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I. INTRODUCTION

Sagent Pharmaceuticals, Inc. ("Sagent") respectfully moves to reopen the captioned cases for purposes of:

> (i) enforcing its settlement agreement with Helsinn Healthcare S.A. ("Helsinn");
>
> [redacted]

The agreements, like the above-captioned cases, concern generic versions of Helsinn's branded product ALOXI® injection, which has palonosetron hydrochloride as the active ingredient. Like Sagent, Dr. Reddy's and Sandoz both settled their respective patent infringement litigations with Helsinn. [redacted]

Sandoz and Dr. Reddy's, together with Teva Pharmaceuticals USA, Inc. ("Teva"), were the first ANDA sponsors to challenge at least one *Orange Book* patent listed for ALOXI®, and thus share the 180-day exclusivity. Teva was the first to trigger that exclusivity, launching its generic ALOXI® "at-risk" (*i.e.*, without a settlement agreement with Helsinn) on March 23, 2018.

Under their agreements with Helsinn, Dr. Reddy's launched on March 26th and Sandoz a few days later on April 2nd.

Helsinn has steadfastly tried to protect its market for ALOXI®, filing infringement actions against at least fourteen other ANDA sponsors in addition to Teva, Dr. Reddy's, Sandoz, and Sagent. Helsinn also tried to enjoin Teva's launch, but was denied. Surprisingly, Helsinn has not sought to remove Dr. Reddy's or Sandoz from the market, [redacted].

Importantly, Sagent's settlement with Helsinn [redacted]

Helsinn disagrees with Sagent's interpretation and [redacted]. Moreover, the applicable court order, as requested, will also ensure compliance, [redacted] We thus seek the Court's assistance.

II. STATEMENT OF FACTS

A. Helsinn Sues Sagent, Among Others, For Patent Infringement on ALOXI® (palonosetron HCl injection).

Helsinn owns New Drug Application ("NDA") No. 021372, which is directed to palonosetron hydrochloride injection and which Helsinn markets in the United States under the ALOXI® trade name. In connection with its NDA, Helsinn listed several patents with the U.S. Food & Drug Administration ("FDA") for publication in *Approved Drug Products with Therapeutic Equivalence Evaluations*, which is commonly known as the "Orange Book." Such patents included those asserted in the instant cases, namely U.S. Patent Nos. 7,947,724; 7,947,725; 7,960,424; 8,598,219; and 8,729,094 (collectively, "the Asserted Patents").

On January 11, 2016, Helsinn filed the first action against Sagent (Civ. A. No. 16-173), after receiving notification that Sagent's Abbreviated New Drug Application ("ANDA") No. 205870, which referenced Helsinn's NDA, contained a so-called Paragraph IV Certification to each of the Asserted Patents. Helsinn filed a second complaint on February 8, 2016 (Civ. A. No. 16-681) (collectively, "the Litigations"), after receiving a similar notification as to Sagent's ANDA No. 204289. [redacted]. Both ANDAs are directed to the dosage strength of Eq. 0.25 mg/base 5 mL (Eq. 0.05 mg base/mL).

Importantly, both ANDAs have received tentative approval from FDA, meaning that the drug products described in the applications are ready for final market approval but for a blocking exclusivity.[1] 21 U.S.C. § 355(j)(5)(B)(iv)(II)(dd); *see also* 21 C.F.R. 314.3(b). That exclusivity

[1] ANDA No. 204289 obtained tentative approval on August 7, 2017, and ANDA No. 205870 obtained tentative approval on April 20, 2018. *See* Exs. 1 and 2. (The Exhibit Nos. correspond to the exhibits listed in the Declaration of Roshan P. Shrestha, Ph.D. ("Shrestha Decl.") submitted herewith.

is the 180-day market exclusivity, which is granted to the first ANDA sponsors to file an application with a Paragraph IV Certification to a patent listed in the Orange Book for the reference listed drug. 21 U.S.C. § 355(j)(5)(B)(iv); *see also* 21 C.F.R. 314.3(b).

Here, that exclusivity is shared by Teva, Dr. Reddy's, and Sandoz, all of which have launched their respective generic ALOXI® in the same dosage strength as Sagent's ANDAs, thus triggering the 180-day exclusivity. No other ANDA sponsor, including Sagent, will be granted final FDA approval until that exclusivity is exhausted. As detailed below, that exclusivity expires on September 19, 2018 [redacted]

B. Sagent and Helsinn Settled the Litigations

On July 25, 2016, Helsinn and Sagent signed a Settlement and License Agreement (the "Sagent Settlement"), resolving the Litigations between them. *See* Ex. 3. Accordingly, both actions were dismissed on August 3, 2016 (Ex. 4, D.I. 39 for Action No. 16-173, and Ex. 5, D.I. 27 for Action No. 16-681) pursuant to a Consent Judgment and Dismissal that was substantially the same in both Litigations, referencing the Sagent Settlement and noting that the "court retains jurisdiction over Helsinn and Sagent for purposes of enforcing this Consent Judgment and Dismissal Order." (the "Sagent Dismissal Orders"); see also, Ex. A to the Sagent Settlement (Ex. 3), specifying the terms of the consent judgment and dismissal order.

Under the terms of the Sagent Settlement, [redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[2] Another such circumstance is where [redacted]

[redacted]

C. Teva Launches the First Generic ALOXI® At-Risk

Before Sagent, Teva also had filed an ANDA referencing Helsinn's NDA for ALOXI® and, over time, with a Paragraph IV Certification to each of the Asserted Patents.[3,4] As noted

[3] Teva's ANDA (like Sandoz's and Dr. Reddy's) was filed on May 27, 2011. *See* Ex. 8 (FDA's list of first applicants, noting the filing date relevant to ALOXI®). As Teva, Dr. Reddy's, and Sandoz share the 180-day exclusivity, it necessarily follows that all three filed on this date. 21 U.S.C. § 355(j)(5)(B)(iv)(II)(bb). Accordingly, Helsinn's first lawsuit against generic ALOXI® sponsors was against Teva, Dr. Reddy's, and Sandoz. *See Helsinn Healthcare S.A. v. Dr. Reddy's Laboratories, Ltd.*, Civ. A. No. 3:11-cv-03962 (D. N.J. filed July 8, 2011) (asserting the '724 and '725 patents).

[4] When Teva's, Dr. Reddy's, and Sandoz's ANDAs were filed, the *Orange Book* listed only the '724 and '725 patents. The remaining Asserted Patents were listed later, requiring the ANDA

above, Teva was one of the first ANDA sponsors to file such an ANDA, entitling Teva to share the 180-day exclusivity with Dr. Reddy's and Sandoz. Teva's ANDA No. 090713 received final FDA approval on March 23, 2018, and Teva launched the same day. *See* Ex. 9, Teva's Press Release dated March 23, 2018 at p. 4 (noting the shared exclusivity). Helsinn was denied an injunction to stop Teva's launch. Ex. 10, Civ. A. No. 14-4274, D.I. 89 (D. N.J. Jan. 30, 2018). To date, Sagent is not aware of any settlement agreement between Helsinn and Teva, thus making Teva's launch "at-risk" for patent damages.[5] As detailed below, Teva's launch triggered Dr. Reddy's and Sandoz's entry into the market, [redacted]

D. Dr. Reddy's and Sandoz Both Launch Generic ALOXI® [redacted]

As noted above, Helsinn sued Teva, Dr. Reddy's, and Sandoz in the same complaint in its initial action against the first sponsors of generic ALOXI® followed by later-filed cases against the same three sponsors after receiving notice of Paragraph IV Certifications to the patents subsequently listed in the *Orange Book*. In late 2014, Helsinn and Sandoz resolved their dispute,

sponsors to file Paragraph IV Certification to each of those patents to secure final FDA approval before patent expiration. When Helsinn was notified of those certifications, it filed suit accordingly. These details are not needed for the instant motion but are provided to ensure an accurate recitation of facts. *See, e.g., Helsinn Healthcare S.A. v. Dr. Reddy's Laboratories, Ltd.*, Civ. A. No. 3:11-cv-05579 (D. N.J. filed Sep. 23, 2011) (asserting the '424 patent against all three first applicants); *Helsinn et al. v. Dr. Reddy's et al.*, Civ. A. No. 3:13-cv- 05815, D.I. 27 (D. N.J. filed Sep. 30, 2013) (asserting the '219 patent against all three first applicants); *Helsinn et al. v. Dr. Reddy's et al.*, Civ. A. No. 2:14-cv-04274, D.I. 1 (D. N.J. filed Jul. 7, 2014) (asserting the '094 patent against Teva and Dr. Reddy's but not Sandoz).

[5] The Court of Appeals for the Federal Circuit has held invalid the asserted claims of four of the Asserted Patents, on which Helsinn has filed a petition for a writ of certiorari. *Helsinn Healthcare S.A. v. Teva Pharms. USA, Inc.*, 355 F.3d 1356 (Fed. Cir. 2017). Helsinn continues to assert the remaining Asserted Patent, the '094 patent, against Teva. *See* Civ. A. No. 3:14-cv-06341 (D. N.J. filed Oct. 13, 2014) now consolidated with 2:14-cv-04274.

executing a settlement agreement and resulting in Consent Judgment and Dismissal Order, which expressly enjoined Sandoz:

> from manufacturing, using, offering to sell or selling within the United States, or importing into the United States, any generic palonosetron hydrochloride injections (Eq. 0.075 mg base/1.5 mL (Eq. 0.05 mg base/mL) and/or Eq. 0.25 mg base/5 mL (Eq. 0.05 mg base/mL)) that are the subject of ANDA No. 202521 ***except as permitted*** by the Settlement and License Agreement that the Parties have entered into.

Order dated Dec. 30, 2014 at pp. 3-4 in Civil Action No. 2-11-cv-03962 (D.I. 247) (Ex. 11, the "Sandoz Order") (emphasis added). Sandoz's settlement allowed it to launch on September 30, 2018, or earlier under certain circumstances. Ex. 12 at p.1. Such circumstance arose, as Sandoz launched on April 2, 2018 (Ex. 13 at p. 2) the same dosage strength as Sagent's ANDAs [redacted]. Although Sandoz's FDA approval letter did not confirm the 180-day exclusivity at that time, there also was no confirmation of forfeiture either. Ex. 14 (Sandoz's final FDA approval letter).

Dr. Reddy's facts are similar. On October 6, 2015, Helsinn likewise signed a settlement agreement with Dr. Reddy's, later dismissing their case with Dr. Reddy's enjoined:

> from manufacturing, using, offering to sell or selling within the United States, or importing into the United States, any generic palonosetron hydrochloride injections (Eq. 0.075 mg base/1.5 mL (Eq. 0.05 mg base/mL) and/or Eq. 0.25 mg base/5 mL (Eq. 0.05 mg base/mL)) that are the subject of ANDA No. 201533 ***except as permitted*** by the Settlement and License Agreement that the Parties have entered into.

Ex. 15 at p. 2 (Stipulation of Dismissal entered Oct. 16, 2016 in Civ. A. No. 2-11-cv-03962, D.I. 355) (the "Dr. Reddy's Order") (emphasis added). Like Sandoz, Dr. Reddy's settlement allowed it to launch "on September 30, 2018 or earlier under certain circumstances." Ex. 16 at p. 1, Helsinn's Press Release dated Oct. 13, 2015. Such circumstance indeed arose, as Dr. Reddy's launched its generic ALOXI®, in the same dosage strength as Sagent's ANDAs, on or prior to March 26, 2018 (Ex. 7), [redacted] Finally, Dr. Reddy's

approval letter confirmed the 180-day exclusivity. Ex. 17 at p. 2 (stating that "Dr. Reddy's is eligible for 180 days of shared generic drug exclusivity for Palonosetron Hydrochloride Injection . . . 0.25 mg (base)/5 mL").

E. Sagent Requested Helsinn to Confirm [redacted]

As Helsinn's "permission" was expressly required for Sandoz and Dr. Reddy's to launch (as they did) before September 30, 2018, [redacted]

On April, 4, 2018, Helsinn responded [redacted]

[6] By contacting Helsinn [redacted] Sagent acted without delay. The same is true as to filing the instant motion [redacted].

[7] [redacted]. Ex. 21.

[redacted]

On the same date, April 4, 2018, Sagent requested Helsinn's [redacted] Sagent's counsel followed up with Helsinn's counsel by email on April 11th and 16th, connecting by telephone on April 17th. Ex. 23, Email thread between Messrs. Auten, Dittmann, and O'Malley dated Apr. 16, 2018.

[redacted] on April 25, 2018, [redacted] (Ex. 24, Ltr. from S. Auten to E. Dittmann *et al.* dated Apr. 25, 2018), [redacted] Ex. 25, Email from E. Dittmann to S. Auten dated Apr. 27, 2018. On May 3, 2018, Sagent again requested Helsinn's consent to [redacted]. Ex. 26, Email follow up from S. Auten to E. Dittmann *et al.* dated May 4, 2018. On May 8, 2018, Helsinn [redacted] (Ex. 20, Email from E. Dittmann to S. Auten dated May 8, 2018), leading to the instant motion.

F. Dr. Reddy's [redacted]

Separately, Sagent also wrote to outside counsel of record for Dr. Reddy's and Sandoz, [redacted] Ex. 27, Ltr. from S. Auten to A. Miller dated Apr. 4, 2018 (Dr. Reddy's); and Ex. 28, Ltr. from S. Auten to E. Abraham dated Apr.

5, 2018 (Sandoz). Counsel for Dr. Reddy's [redacted] Ex. 29, Email from F. Rodriguez to S. Auten dated Apr. 25, 2018. [redacted] (Ex. 30, Email from E. Abraham to S. Auten dated Apr. 19, 2018), and [redacted] Ex. 31, Ltr. from S. Auten to M. Quinn *et al*. dated Apr. 19, 2018; and Ex. 32, Email from S. Auten to M. Quinn dated Apr. 25, 2018.

G. Sagent Faces Irreparable Harm [redacted]

Sagent will suffer irreparable harm [redacted]. Declaration of Donald R. Bullock at ¶ 21 ("Bullock Decl."). [redacted] *Id*. at ¶ 22.

[redacted] *Id*. at ¶ 24.

[redacted]

[redacted] *Id.* at ¶¶ 25, 29.

Further, only the following three other ANDA sponsors have tentative approval at present and have settled their cases with Helsinn: Aurobindo Pharma Ltd.; Akorn, Inc.; and Somerset Therapeutics, LLC. As of today, they are the only other ANDA sponsors able to receive final FDA approval at the same time as Sagent, once the 180-day exclusivity expires. *Id.* at ¶ 31. But additional competition is expected in the future, as Helsinn is known to have sued at least fourteen other ANDA sponsors. That means an additional eleven other ANDAs (or more) could also receive final approval in the future, assuming their applications meet FDA requirements. *Id.* [redacted]

[redacted]

III. LEGAL STANDARD

A. Enforcement of Settlement Agreements

Federal courts have the inherent power to enforce settlement agreements. *See Kelly v. Greer*, 365 F.2d 669, 671 (3d Cir. 1966) (collecting cases). Indeed, there is a strong public policy favoring settlement, and requiring parties to honor settlement agreements. *See Honeywell v. Bubb*, 130 N.J. Super. 130, 135-36 (App. Div. 1974) ("Embedded in our jurisprudence is the principle that the settlement of litigation ranks high in our public policy . . . Thus, barring fraud or other compelling circumstances, our courts strongly favor the policy that the settlement of litigation be attained and agreements thereby reached, be honored."); *Nolan v. Lee Ho*, 120 N.J. 465, 472 (1990). Here, the Sagent Dismissal Order specifically provides that this Court retain jurisdiction over the parties for the purposes of enforcing the consent judgment and dismissal order, which were included within the Sagent Settlement. *See e.g.*, Ex. 4, Civ. A. No. 16-173, D.I. 39 at p. 3; *Halderman v. Pennhurst State School & Hosp.*, 901 F.2d 311, 317 (3d Cir. 1990). Further, [redacted]. *Floyd v. U.S.*, Civ. A. 15-6371, 2015 WL 5090096 at *fn. 5 (D.N.J. Aug. 26, 2015) ([redacted]) *citing Groupe SEB USA, Inc. v. Euro-Pro Operating LLC*, 774 F.3d 192, 197 (3d Cir. 2014) ([redacted]).

B. Interpretation of the Settlement Agreement

Settlement agreements are interpreted as binding contracts. *In re Columbia Gas Sys. Inc.*, 50 F.3d 233, 238 (3d Cir. 1995). Interpreting a settlement agreement presents a question of contract law, in which the primary object is to give effect to the intention of the parties. *Id*. at 241 (internal citations omitted); *Coltec Industries v. Hobgood*, 280 F.3d 262, 269 (3d Cir. 2002) ("[B]asic contract principles . . . apply to settlement agreements"). Absent clear language in the settlement agreement to resolve a dispute over the proper construction of a contract, a court may go outside the four corners of the contract and consider extrinsic and parol evidence presented by the parties. *In re Columbia,* 50 F.3d 233, 241. [redacted]

IV. ARGUMENT

A. Dr. Reddy's and Sandoz's Launches

[redacted] Ex. 3, [redacted]. [redacted] Ex. 17 at p. 2; Ex. 14 at p. 2. The only dispute is whether their launches

were [redacted].

Helsinn contends [redacted]. Ex. 19. But that conclusion is belied by the following facts. First, t[redacted].

Second, if these launches [redacted]. *See, e.g., Valmed Mgmt. Corp. v. Jess Med. Sys.*, Civ. A. No. A-2947-05T1, 2007 WL 148752, at *6 (N.J. Super. Ct. App. Div. Jan. 23, 2007) [redacted].

For comparison, shortly before Teva launched its product at-risk, [redacted].

[8] Other ANDA defendants sued by Helsinn in this District or Delaware include: Aurobindo Pharma Ltd. (D. Del. 13-688), Ben Venue/Eurohealth (D. Del. 13-1612), Accord Healthcare, Inc. (D. Del. 13-2101), Cipla, Ltd. (D. Del. 14-427), Hospira, Inc. (D. Del. 15-264); Gavis Pharma, LLC (D.

[redacted] Bullock Decl. at ¶ 9-10. [redacted]

This is almost assuredly because [redacted]

B. The Court Should Compel the [redacted]

The Sagent Settlement [redacted] It is undisputed that Helsinn has entered into a settlement agreement with both Dr. Reddy's and Sandoz and as explicitly stated in their respective dismissal orders. *See* Ex. 15 at p. 2 and Ex. 11 at p. 4,

N.J. 15-1228), Mylan Inc. (D. Del. 14-709), Par Pharmaceutical Cos. (D. N.J. 15-2078), Qilu Pharmaceutical Co., Ltd. (D. N.J. 15-8132), Emcure Pharmaceuticals, Inc./Heritage Pharma Labs, Inc. (D. N.J. 15-7015); Akorn, Inc. (D. N.J. 16-173); Ingenus Pharmaceuticals, LLC (D. N.J. 16-173); Virtus Pharmaceuticals, LLC (D. N.J. 17-3216), Zydus Pharmaceuticals USA, Inc. (D. N.J. 16-4239).

respectively. Further, it is established that [redacted]

In the first scenario, [redacted] Therefore, the Court [redacted]

C. [redacted]

[redacted]. Ex. 25, Email from E. Dittmann dated April 27, 2018. [redacted]. *Pfizer et al. v. Mylan et al.*, Civ. A No. 10-CV-03246, 2012 WL 1303438 (D. N.J. Jan. 4, 2012); *see also Thomas & Marker Constr. Co. v. Wal-Mart Stores, Inc.*, Civ. A. No. 06-406, 2008 WL 3200642, at *3 (S.D. Ohio Aug. 6, 2008) (c[redacted]; *Sonnino v. Univ. of Kan. Hosp. Auth.*, Civ. A. No. 02-2576, 2004 WL 769325, at *3 (D. Kan. April 8, 2004) ([redacted]

[redacted]). As noted by Magistrate Judge Arpert, "[redacted]" *Wyeth v. Orgenus Pharma Inc.*, Civ. A. No. 09-3235 (FLW), 2010 WL 4117157, at *4 (D. N.J. Oct. 19, 2010) (internal citations omitted).

[redacted].

D. Sagent will Suffer Irreparable Harm [redacted]

1. [redacted]

A manufacturer that is prevented from entering the market at the earliest possible date, because a competitor is permitted to capture an early market entry, is at a distinct disadvantage. *See, Mova Pharm. Corp. v. Shalala*, 955 F. Supp. 128, 131(D. D.C. 1997), *aff'd*, 140 F.3d 1060 (D.C. Cir. 1998). Both of Sagent's ANDAs have tentative approval [redacted]. Exs. 1, 2, and 21. [redacted]

[redacted]

[redacted] *Id.* at ¶ 23. [redacted]

[redacted] *Id.* at ¶¶ 22-23.

[redacted] *Id.*

[redacted] *Id.* at ¶¶ 25, 27-30.

[redacted] *Id.* at ¶ 31. At present, only three other ANDA sponsors have tentative approval and have settle their cases with Helsinn, and [redacted]. But because Helsinn has sued at least fourteen other ANDA sponsors, then as many as eleven other ANDAs (or more) could also receive final approval in the future. [redacted]

Id. at 32.

2. The Sagent Settlement Includes [redacted] Bullock Decl. at ¶ 33. Helsinn is [redacted] Sagent [redacted] *Id.*; Ex. 3 at § 3.4(b). [redacted]

V. CONCLUSION

For the reasons detailed above, Sagent respectfully requests for these actions to be reopened for the limited purpose of requiring enforcement of the Sagent Settlement [redacted]. Sagent also respectfully requests this Court [redacted].

Dated: May 11, 2018

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